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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/048,205	05/02/2002	Richard A Gambale	B 0410/7284	4832
22832	7590	06/21/2004		
KIRKPATRICK & LOCKHART LLP				
75 STATE STREET				
BOSTON, MA 02109-1808				
EXAMINER				
JACKSON, SUZETTE JAMIE				
ART UNIT		PAPER NUMBER		
3738				

DATE MAILED: 06/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/048,205

Applicant(s)

GAMBALE, RICHARD A

Examiner

Suzette J Jackson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 March 2004.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5, 7-14 and 16-24 is/are pending in the application.
- 4a) Of the above claim(s) 19-21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 7-14, 16-18 and 22-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- 1) ☐ Certified copies of the priority documents have been received.
 - 2) ☐ Certified copies of the priority documents have been received in Application No. _____.
 - 3) ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 3/18/04
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

1. Applicant's amendment dated 3/18/04 has been received in application serial number 10/048,205.

Election/Restrictions

2. Newly submitted claims **19-21** are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Claims **19-21** are directed towards a delivery apparatus in Classified in **class 606, subclass 108**. The inventions are distinct because they have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

3. Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims **19-21** are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 1, 3, 7, and 24 are rejected under 35 U.S.C. 102(e) as being anticipated by Ahern 6,620,170. Ahern discloses the invention as claimed noting figure 7 comprising: A tissue implant made of a flexible helical spring formed from a filament (42) having rectangular cross-section profile (col. 11, lines 21-22) having a plurality of coils, each having a edge along which is formed at least one *barb/projection edge* that engages surrounding tissue; wherein the barb faces radially outward from the spring; wherein the wire is oriented in an acute angle to the longitudinal axis which allows the barb/projection edge to claw into tissue to serve as an anchoring mechanism.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 2, 4-5, and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ahern 6,620,170. Ahern has been disclosed above however Ahern does not specify a barb that is proximally facing; and or proximally facing away from the spring or a barb with a rounded contour. Applicant has not disclosed that having rounded barbs or barbs that face in a proximal direction away from the spring solves any stated problem or is for any particular purpose. Moreover it appears that the *barb/projection edge* of Ahern would perform equally as well as the barbs that are rounded or face in a proximal direction. Accordingly, the use of rounded barbs or barbs which face in a proximal direction away from the spring is deemed to be a design consideration which fails to patentably distinguish over the prior art of Ahern.

8. Claims 8-11 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ahern in view of Lashinski et al. 5,868,780. Ahern has been disclosed above however Ahern does not specify that the spring device be formed from a plurality of materials each having different moduli of elasticity; varying along the springs length. Lashinski et al. teaches that stents can be formed with different materials, varied along the length of the device, which have different yield strengths and having different moduli of elasticity. It would have been obvious to one having ordinary skill in the art at the time the invention was made to take the device of Ahern and manufacture it with different materials having various moduli of elasticity because it would allow the device to plastically conform to the anatomy of the passageway in which it is to placed.

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9. Claims 12-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ahern in view of Khosravi et al. 6,425,915. Ahern has been disclosed above however Ahern does not disclose manufacturing from a flat sheet of material and wound into a spring configuration and forming a barb by etching process. Khosravi et al. teaches that stents can be made from a flat sheet of nitinol by chemical etching and then rolled to form a coil member (col. 6, lines 17-46). It would have been obvious to one having ordinary skill in the art at the time the invention was made to take the device of Ahern and form it from the process taught by Khosravi et al. because it would form a thin band for small insertion areas and is a well know process for manufacturing tubular medical prosthesis.

10. Claims 14 and 16-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ahern in view of Summers 5,607,445. Ahern has been disclosed above noting figure 7 and barb/projection edge, however Ahern does not specify *photochemical etching* process. Summers teaches manufacturing a coil device by photo-etching process (col. 9, lines 31-45). It would have been obvious to one having ordinary skill in the art at the time the invention was made because chemical/photo etching are well known methods for forming loops and coils from a blanks to make tubular prosthesis.

Response to Arguments

11. Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.


Conclusion

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

13. A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **WO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suzette J. Jackson whose work schedule is Monday-Friday 9-6:30 off every other Friday and whose telephone number is 703-308-6516.
15. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306.
16. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.


Suzette J. Jackson
17 June 2004